

Application No. 09/768,991  
Amendment dated April 5, 2004  
Reply to Office Action of October 3, 2003

### REMARKS

Applicant amended claims 1, 30, 44, and 48 and added new claims 199-204 to further define Applicant's invention. New claims 199-204 are supported by the specification at least on page 4, lines 16-18 and Fig. 8.

In the Office Action, the Examiner rejected claims 1-16, 18-25, 119-123, 149, 153-159, and 195 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner rejected claim 1 because the phrase "said plurality of bone screw receiving holes" lacks antecedent basis. Applicant deleted the phrase from claim 1. Applicant submits that this rejection is overcome.

The Examiner rejected claims 1-14, 18-34, 37-52, 56-71, 74-91, 94-109, 112-150, and 152-198 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,432,106 to Fraser in view of U.S. Patent No. 6,066,175 to Henderson et al. and U.S. Patent No. 6,214,005 to Benzel et al. Applicant respectfully traverses the rejection for at least the following reasons:

I. Fraser, Henderson et al., and Benzel et al. Fail To Teach An Implant With a Trailing End Adapted For Use With Bone Screws Having A Maximum Height Adapted To Fit Within The Disc Space.

Independent claims 1, 26, 44, 62, 81, and 100 recite an implant with a trailing end adapted for use with bone screws, the trailing end having a "maximum height" as measured "along the longitudinal axis of the human spine" that is "adapted to fit within the disc space and between the vertebral bodies adjacent to the disc space." No such structure is taught, disclosed, or suggested by Fraser, Henderson et al., and Benzel et al. whether alone or when properly combined.

In Figs. 1-3 and 8, Fraser discloses a fusion cage adapted for use with bone screws through a plate 20 having tabs 36', 38', 40', and 42' with bone screw receiving holes therein. (See Fraser, Abstract and col. 3, lines 7-17; Fig. 2). The trailing end of the Fraser fusion cage includes plate 20 which has a height measured along the longitudinal axis of the human spine that is greater than the distance between the adjacent vertebral bodies. The trailing end of the Fraser fusion cage shown in Figs. 1-3 and 8 is not adapted to fit within the disc space and between the vertebral bodies

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adjacent to the disc space. In Figs. 4-6 and 9, Fraser discloses a fusion cage that is not adapted to receive bone screws through the trailing end. The embodiment of these figures does not teach Applicant's claimed invention.

Henderson et al. disclose a fusion chamber having a trailing end portion 107 with a maximum height that is greater than the height of the disc space into which the implant is inserted. Trailing end 107 includes upper and lower flanges 109 that extend outside of the disc space. (Henderson et al., col. 10, lines 46-53; Fig. 12). The flanges are configured to conform to the exterior aspect of the adjacent vertebrae outside of the disc space. (Henderson et al., Fig. 14). The trailing end disclosed by Henderson et al. is not adapted to fit within the disc space and between the vertebral bodies adjacent to the disc space.

Benzel et al. discloses a spinal column retaining apparatus including a pair of rods (12, 14) and plates (30, 32) which engage the rods along vertical axis A of the human body. Each rod has a length "which is sufficient to enable the rods to span at least the two vertebrae V1 and V2." (Benzel et al., col. 2, lines 23-35, 54, and 55 and Fig. 1). Plates 30, 32 have inner side surfaces (64, 164) adapted to engage the anterior surface of the vertebrae. (Benzel et al., col. 3, lines 1-5; and col. 6, lines 6-11). Each of the plates of Benzel et al. does not have a trailing end with an upper edge and a lower edge having maximum height therebetween as measured along the longitudinal axis of the spine that is adapted to fit within the disc space and between the vertebral bodies adjacent to the disc space as recited in Applicant's claimed invention.

II. Many of the Independent Claims Recite Additional Features Not Taught or Suggested by Fraser, Henderson et al., and Benzel et al.

Applicant further submits that independent claims 1, 44, 62, 81, and 100 each recite other features not taught or suggested by Fraser, Henderson et al., and Benzel et al. whether alone or when properly combined. Independent claim 1 recites a spinal implant with a leading end and a trailing end opposite the leading end, the trailing end having upper and lower edges and a plurality of bone screw receiving holes, at least one of the bone screw receiving holes being adapted to permit the trailing end of a bone screw to "protrude beyond said one of said edges of said implant and overlie at

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least in part one of the adjacent vertebral bodies" No such structure is taught, disclosed, or suggested by Fraser, Henderson et al., and Benzel et al. whether alone or when properly combined. For the apparatus disclosed by Benzel et al. in particular, each plate 30a does not have upper and lower edges that are adapted to be oriented toward the adjacent vertebral bodies. At least one of the edges is positioned completely outside of the disc space and is therefore not oriented toward any vertebral body. (See, e.g., Benzel et al., Fig. 9). To the extent that screw in the Benzel et al. device extends beyond the edge, it extends into the disc space and does not overlie one of the adjacent vertebral bodies as recited in amended claim 1.

Independent claim 44 recites a trailing end having a maximum height, the trailing end "being adapted to receive at least a portion of a bone screw passing therein that extends beyond said maximum height immediately adjacent thereto" and overlies at least in part one of the adjacent vertebral bodies. No such structure is taught, disclosed, or suggested by Fraser, Henderson et al., and Benzel et al. whether alone or when properly combined. The trailing ends disclosed by Fraser, Henderson et al., and Benzel et al. receive bone screws having portions immediately adjacent the trailing end that are within the maximum height of the respective trailing end. (See, e.g., Fraser, Fig. 2; Henderson et al., Fig. 14). For the apparatus disclosed by Benzel et al. in particular, Figs. 2 and 9 show that the portions of fasteners 38, 40, and 42 immediately adjacent the trailing end are all well within the maximum height of the trailing end of the apparatus. To the extent that screw in the Benzel et al. device extends beyond the edge, it extends into the disc space and does not overlie one of the adjacent vertebral bodies as recited in amended claim 44.

The Examiner contends that Henderson et al. show a trailing end adapted to receive at least a portion of a bone screw passing therein that extends beyond the maximum height immediately adjacent thereto in Figs. 1-16. (Office Action, page 5, first paragraph). Applicant respectfully disagrees with the Examiner's contention. Henderson et al. do not show the structure of Applicant's invention as recited in claim 44.

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Independent claim 62 recites that the maximum height of the trailing end is "adapted to be less than the sum of the maximum diameter of two bone screws adapted to be inserted in said bone screw receiving holes." No such structure is taught, disclosed, or suggested by Fraser, Henderson et al., and Benzel et al. whether alone or when properly combined. For the apparatus disclosed by Benzel et al. in particular, Figs. 2 and 9 show that the maximum height of the trailing end of apparatus 10 is greater than the sum of the maximum diameter of any two of fasteners 38, 40, and 42.

Independent claim 62 further recites "at least one of said bone screw receiving holes interrupting only said upper edge of said trailing end, and another one of said bone screw receiving holes interrupting only said lower edge of said trailing end." No such structure is taught, disclosed, or suggested by Fraser, Henderson et al., and Benzel et al. whether alone or when properly combined. For the apparatus disclosed by Benzel et al. only the interior edge between the upper and lower portions of the apparatus is interrupted by a bone screw receiving hole. In particular, Figs. 2 and 9 of Benzel et al. show that the upper and lower portions of the apparatus are not interrupted by any bone screw receiving holes.

Independent claim 81 recites at least one of a plurality of bone screw receiving holes passing through the exterior surface and one of the upper and lower edges of the trailing end "so as to permit the bone screw to protrude over one of said edges within a plane of said trailing end." No such structure is taught, disclosed, or suggested by Fraser, Henderson et al., and Benzel et al. whether alone or when properly combined. For the apparatus disclosed by Benzel et al. in particular, Figs. 2 and 9 show that the upper and lower portions of the apparatus do not permit a bone screw to protrude over one of the portions within a plane of the trailing end.

Independent claim 100 recites a trailing end having an outer perimeter with an upper edge and a lower edge, each of the upper and lower edges of the outer perimeter having a single gap therein for permitting a portion of a bone screw to protrude over the respective edge of the perimeter. No such structure is taught, disclosed, or suggested by Fraser, Henderson et al., and Benzel et al. whether alone or when properly combined. For the apparatus disclosed by Benzel et al. only the interior edge between

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the upper and lower portions of the apparatus is interrupted by a bone screw receiving hole. In particular, Figs. 2 and 9 of Benzel et al. show that the upper and lower portions of the apparatus are not interrupted by any bone screw receiving holes.

III. The combination of Fraser, Henderson et al., and Benzel et al. is Improper.

A. The motivation used to support the combination of references is inapplicable.

Applicant respectfully submits that the motivation used to support the combination of Fraser with Henderson et al. is inapplicable. The Examiner states in the Office Action that "given the teaching of Henderson et al. it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the screw holes of Henderson et al., in the fusion cage of Fraser to fasten the fusion cage to the vertebrae." (See Office Action, page 4, first full paragraph). Applicant respectfully submits that the Examiner's asserted motivation is inapplicable because Fraser already accomplishes without modification what the Examiner states is the reason to combine the teachings of Henderson et al. with Fraser, i.e., incorporating screw holes in Fraser. (See, e.g., Fraser, Fig. 2, bone screw holes 36, 38, 40, and 42). The combination of Fraser with Henderson et al. does not add anything further to the Fraser device.

Applicant also respectfully submits that the motivation used to support the combination of Fraser and Henderson et al. with Benzel et al. is inapplicable. The Examiner states in the Office Action that "given the teaching of Benzel et al. it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the partially circumferentially screw holes in the device Fraser/Henderson et al., to block movement of the implant, and thereby its associated vertebral portions." (See Office Action, page 4, last full paragraph). Applicant respectfully submits that the Examiner's asserted motivation is inapplicable because Fraser and Henderson et al. each already accomplish without modification what the Examiner states is the reason to combine the teachings of Benzel et al. with Fraser and Henderson et al., i.e., blocking the movement of the implant relative to the associated vertebral portions. (See, e.g., Fraser, Figs. 3 and 8, bone screws 46, 48; and Henderson et al., Fig. 14, bone screws 123).

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B. Henderson et al. teach away from Benzel et al.

Applicant further submits that the proposed combination of Henderson et al. with Benzel et al. is untenable because Henderson et al. teach away from the screw hole arrangement of Benzel et al. Henderson teaches that it is preferable and advantageous to use flanges with the implant. (See, e.g., Henderson et al., col. 9, lines 30-39). To modify the trailing end of Henderson et al. to include bone screw holes as taught by Benzel et al. instead of flanges would be contrary to the teachings of Henderson et al. (See MPEP § 2145(X)(D), page 2100-152, 2<sup>nd</sup> col. (August 2001)).

C. The Proposed Modification Renders The Combination Unsuitable For Its Intended Purpose

Fraser and Henderson et al. each teach screw holes that angle the bone screw away from the longitudinal axis of the implant at each of the top and bottom surfaces of the implant. (See, e.g., Fraser, Fig. 3 and Henderson et al., Fig. 9). Benzel et al. teach screw holes that position bone screws either parallel to or at an angle toward the longitudinal axis of the plate. (See, e.g., Benzel et al., Figs. 2 and 10). Modifying the screw holes of Fraser and Henderson et al. as taught by Benzel et al. would render the Fraser and Henderson et al. devices unsuitable for their intended purpose because positioning bone screws parallel to or at an angle toward the longitudinal axis of the implant of either Fraser or Henderson et al. would fail to provide adequate anchoring of the implant to the adjacent vertebral bodies in a manner consistent with the teachings of Fraser and Henderson et al. Accordingly, Applicant submits that the rejection is improper and must be withdrawn.

With respect to dependent claims 149, 150, and 152, the Examiner contends that Figs. 15 and 16 of Henderson et al. disclose a device where at least one of the bone screw receiving holes passes through the lower edge of the trailing end. (Office Action, page 5, fourth full paragraph). Applicant respectfully disagrees with the Examiner's contention. Claims 149, 150, and 152 each recite at least one of the bone screw receiving holes passing through the upper edge and at least one of the bone screw receiving holes passing through the lower edge of the trailing end. Figs. 15 and 16 of Henderson et al. show screw holes well within the upper and lower edges of the

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device. Henderson et al. do not teach or suggest a bone screw receiving hole passing through either the upper edge or lower edge of the trailing end.

The Examiner rejected claims 15, 16, 35, 36, 53, 54, 72, 73, 92, 93, 110, and 111 under 35 U.S.C. § 103(a) as being unpatentable over Fraser, Henderson et al., and Benzel et al. further in view of U.S. Patent No. 5,364,399 to Lowery et al. Applicant traverses the Examiner's rejection. The Examiner states in the Office Action that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a lock in the device of Fraser/Henderson et al./Benzel to engage the heads of the screws and provide a rigid fixation of the screws to the implant. (Office Action, page 6, third full paragraph). Fraser teaches that the screws used with the fusion cage are "of the 'locking' type, so that they cannot 'back out' of the holes in the plate." (Fraser, col. 3, lines 19-20). Applicant submits that one of ordinary skill in the art would not use a lock as disclosed by Lowery et al. to lock a self-locking screw as disclosed by Fraser. Accordingly, Applicant submits that the combination of Lowery et al. with Fraser, Henderson et al., and Benzel et al. is improper and must be withdrawn.

Applicant submits that independent claims 1, 26, 44, 62, 81, and 100 are allowable and that dependent claims 2-16, 18-25, 27-31, 33-25, 27-43, 45-54, 56-61, 63-80, 82-99, 101-150, and 152-198 are allowable at least because they depend from an allowable independent claim, or claims dependent therefrom. Applicant submits that the rejections of claims 1-16, 18-31, 33-54, 56-80, 82-99, 101-150, and 152-198 over the art of record have been overcome. Applicant also submits that new claims 199-204 are allowable over art of record at least due to their dependency from an allowable independent claim.

In view of the foregoing remarks, It is respectfully submitted that the claims, as amended, are patentable. Therefore, it is requested that the Examiner reconsider the outstanding rejections in view of the preceding comments. Issuance of a timely Notice of Allowance of the claims is earnestly solicited.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including

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any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-1066.

Respectfully submitted,

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Dated: April 5, 2004

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